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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,579	05/15/2002	Bernt Sweder Van Asbeck	30394-1064	7721

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EXAMINER	
STUCKER, JEFFREY J	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,579	VAN ASBECK ET AL.	
	Examiner	Art Unit	
	Jeffrey Stucker	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office Action is in response to the amendment filed 13 August 2004. Claims 1 and 3-27 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim 19 is used twice and claim 22 has been skipped. Correction is required.

The objection to the specification for informalities **is withdrawn** in view of the amendment.

The new title of the invention is acceptable.

The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of the amendment.

The rejection of claims 1-6 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention **is withdrawn** because the inclusion of an antiviral compound would treat a viral infection. This is not an admission that bleomycin or deferiprone can or do treat HIV-1 *in vivo, per se*.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Tabor et al. (WO 92/16200) **is withdrawn** in view of the amendment.

The rejection of claims 1, 2, 5, and 6 under 35 U.S.C. 102(b) as being anticipated by Malley et al. (PNAS, 1994) **is withdrawn** in view of the amendment.

The rejection of claims 1-4 under 35 U.S.C. 103(a) as obvious over Malley et al. (PNAS, 1994) in view of Sham et al. (WO 97/21683) **is withdrawn** in view of the amendment.

The following are new grounds of rejection necessitated by applicant's amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7-9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohta et al. (Biological & pharmaceutical Bulletin, Feb. 1999, abstract only).

The claims are directed to a composition and method of use comprising bleomycin and a reverse transcriptase anti-viral compound.

Ohta et al. teach that a DNA polymerase inhibitor, KM043 moderately inhibited HIV reverse transcriptase. The reference notes that in the presence of KM043, the cytolytic effect of bleomycin is improved. Therefore, a composition comprising bleomycin and a reverse transcriptase and method of treating HIV infection are anticipated by Ohta et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 7-11 are rejected under 35 U.S.C. 103(a) as obvious over Gompels et al. (AIDS, 1992) in view of Sham et al. (WO 97/21683).

The claimed invention is directed to a composition and its use for treating HIV infection. The composition comprises bleomycin and ritonavir.

Gompels teaches treating an HIV induced disease with bleomycin. Gompels et al. does not specifically recite that bleomycin is used in conjunction with zidovudine (an anti-viral compound) but states that is it is not contra-indicated. (page 1176, second column under methods). This implies that known antiviral agents are also used in conjunction with bleomycin in the disclosed regimen.

Sham et al. teach that ritonavir is approved for treating HIV infection. See the bottom of page 2, as well as throughout the reference. The disclosure also teaches that protease inhibitors should be given in combination with other anti-viral compounds. See page 5. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a known efficacious compound in the claimed composition. One would have been motivated to do this because Sham et al. teach that multivalent treatments are more effective and it would be obvious to combine known compounds with the expectation of inhibiting HIV while treating an HIV induced disease. Thus, the instant invention is obvious over Gompels et al. in view of Sham et al.

Claims 1, 5-9, 12, and 13 are rejected under 35 U.S.C. 103(a) as obvious over Gompels et al. (AIDS, 1992) in view of Sham et al. (WO 97/21683).

The claimed invention is directed to a composition and its use for treating HIV infection. The composition comprises bleomycin and dideoxyinosine.

The relevance of Gompels et al. is set forth above.

Malley et al. teach the use of hydroxamate derivatives in conjunction with dideoxyinosine to synergistically treat HIV

infection. See the abstract and the throughout the text. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a known efficacious compound in the claimed composition. One would have been motivated to do this because Malley et al. teach that multivalent treatments are more effective and it would be obvious to combine known compounds with the expectation of inhibiting HIV while treating an HIV induced disease. Thus, the instant invention is obvious over Gompels et al. in view of Malley et al.

Claims 14-17 and 20-25 are rejected under 35 U.S.C. 103(a) as obvious over Andrus et al. (Biochemical pharmacology, 1998, abstract only) in view of Sham et al. (WO 97/21683).

The claimed invention is directed to a composition and its use for treating HIV infection. The composition comprises deferiprone and ritonavir.

Andrus et al. teach that deferiprone inhibits HIV-1. The reference does not teach ritonavir.

The relevance of Sham et al. is given above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a known efficacious compound such as ritonavir with an anti-HIV

compound. One would have been motivated to do this because Sham et al. teach that multivalent treatments are more effective and it would be obvious to combine known compounds with the expectation of inhibiting HIV while treating an HIV induced disease. Thus, the instant invention is obvious over Andrus et al. in view of Sham et al.

Claims 14,15,18-23, 26, and 27 are rejected under 35 U.S.C. 103(a) as obvious over Andrus et al. (Biochemical pharmacology, 1998, abstract only) in view of by Malley et al. (PNAS, 1994).

The claimed invention is directed to a composition and its use for treating HIV infection. The composition comprises deferiprone and dideoxyinosine.

The relevance of Andrus et al. is given above.

The relevance of Malley et al. is given above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a known efficacious compound such as dideoxyinosine with an anti-HIV compound. One would have been motivated to do this because Malley et al. teach that multivalent treatments are more effective and it would be obvious to combine known compounds with the expectation of inhibiting HIV while treating an HIV

induced disease. Thus, the instant invention is obvious is obvious over Andrus et al. in view of Malley et al.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R.§ 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.

Jeffrey Stucker
JEFFREY STUCKER
PRIMARY EXAMINER